

**(2) REMARKS**

**1. Summary of the Interview**

Applicants appreciate and thank Examiner Fay for the courtesy extended to their representative during a telephonic interview on June 27, 2005. During the interview the rejections under 35 USC §112 and 35 USC §103 were discussed. Agreements were reached as to the next steps to be followed by applicants and the examiner, but no firm commitments were made as to allowable subject matter. In essence, the following summarizes the interview:

- (1) The indefiniteness rejection can be overcome by simply inserting "further" before the listing of additional materials. Thus, it is now clear that these other materials are not defining the ingredients of the base claims.
- (2) The obviousness rejection may be overcome by resubmitting the claims as method of use claims, subject to the examiner conducting a search which does not show that the same compositions, including the key components at the claimed concentrations, have been used before for antibacterial purposes. The examiner also requested that the applicants to confirm that they know of no prior art on this point.
- (3) Applicants repeated their argument that the references don't show the compositions at the claimed concentrations for any use and that the burden of proof has not been properly shifted back to the applicant. Examiner Fay maintained the correctness of her position but said that she would seek the consultation of another examiner when applicants resubmit their arguments.

**2. Rejection under 35 USC §112, second paragraph.**

Claims 2 and 4 have been rejected under 35 USC §112, second paragraph, because there is no antecedent basis in the base claim for the term “at least one member selected from the group consisting of an antiseptic agent, a chelating agent, a buffer, an isotonizing agent, a thickener, a surface active agent and an antibacterial assistant”.

Consistent with the discussion of the interview, the claims are now resubmitted in a form which should remove any basis for this rejection.

Accordingly, withdrawal of this rejection appears in order.

### **3. Rejection under 35 USC §103(a).**

Claims 1-4 have been rejected under 35 USC §103(a) as being unpatentable over The Patent Abstract of Japan 10319358 (Menicon Co., Ltd.) and The Patent Abstract of Japan 10108899 (Tomey Technol. Corp.) for the reason set forth on pages 2 and 3 of the Office Action of January 15, 2003. This rejection is respectfully traversed because the references do not establish a *prima facie* case of obviousness and the evidence of record is sufficient to overcome mere *prima facie* obviousness.

Applicants traverse this rejection directly and present method of use claims to draw claims which more clearly distinguish from the art.

#### **A. New method of use claims are submitted**

Applicants have previously argued that the claimed invention is not obvious from JP-A-10-319358 and/or 10108899, because the concentrations of the polyallylamine and the purpose for the polyallylamine are materially different, the reference does not provide necessary motivation required under 35 USC 103(a) for a person skilled in the art to use polyallylamine in a lower level than that taught by the reference. Applicants further alleged that since the cited reference does not teach or suggest that polyallylamine has an antibacterial activity, the high antibacterial activity of the claimed composition is unexpected from the cited

reference. It was argued that it is not obvious for a person skilled in the art to optimize in an unknown range for a purpose not discussed in the art.

In the most recent Office Action, the Examiner has taken the position that these arguments were not well taken because applicants were claiming a composition and not a process. Accordingly, consistent with the discussion during the telephonic interview, applicants submit new claims 5-8, drawn to the method of use of the composition previously claimed for the purposes previously claimed.

Applicants hereby confirm that, while they do not represent that they have done a search, they know of no prior art on the antimicrobial effects of polyallylamine.

Accordingly, allowance of claims 5-8 appears in order.

**B. Composition Claims 1-4 are Not Rendered *prima facie* Obvious**

Applicants respectfully resubmit the arguments in their last response, without burdening the record with repeating them all here. Applicants emphasize here that the cited references do not provide any motivation or suggestion for a person skilled in the art to arrive at applicants' claimed invention.

The prior art does not in any way teach or suggest the use polyallylamine at below the lowest disclosed, effective concentration. No motivation exists to use a concentration below that level (reducing it significantly to the range claimed by applicants) and look for antibacterial activity – a property not mentioned by the prior art.

The examiner has indicated that the prior art's use of the polyallylamine as a preservative teaches that it "inherently contains some antibacterial activity". However, the statement here relied upon by the examiner is believed to be that in the English abstract of JP-A-10-319358, which incorporates a "specified polyallylamine" to "suppress a change of the base curve of a contact lens at the time of wet preservation and distribution." The stability referred to is the physical shape, not microbiological. In any event, there is no reason for a person skilled in

the art to extend the effective range well below the broadest range of effectiveness taught by the reference.

The references fail to establish *prima facie* obviousness, under the three basic criteria that, according to MPEP §2142, must be met. (1) There is no suggestion or motivation to modify the reference teachings, (2) there would be no reasonable expectation of success for the proposed modification, and (3) the prior art wholly fails to teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Here, these factors are wholly lacking.

The first criteria is not met because there are no specific reasons given – in the references themselves or from any presentation of logic – as to why someone skilled in the art would be motivated to make the modifications necessary to meet the terms of the claims. There is no reasoning given by the examiner on how the person skilled in the art might be motivated from the deficient teachings of the references to modify those teachings for applicants' new purpose and new, lower concentrations. There is no logical reason apparent from either the references or the Office Action as to why the person skilled in the art would put aside the teachings of the references and adapt those teachings to achieve a purpose not taught other than by applicants' own description.

The Office Action also fails to meet the second criteria. There must be a reasonable expectation of success. The rejection simply calls for changing the teachings of the references to use less polyallylamine than its disclosed minimum. There is no reasoning given in the Office Action as to why such a low level would be reasonably expected to work for the disclosed purpose.

Applicants claim use of concentrations of 0.3 to 50 ppm. This range is not disclosed in the prior art, nor is the reason for its use. JP-A-10-319358 teaches

using polyallylamine at much higher concentrations for a different purpose. The art describes concentrations at least 100% higher to suppress curvature change of a contact lens at the time of the distribution. The lowest effective concentration for this purpose is 0.01 w/v % (*i.e.*, not less than 100 ppm), preferably not less than 0.1 w/v.

Applicants' maximum claimed level is less than half of what the reference suggests as the minimum useful for any purpose. Couple this with the fact that the purpose disclosed by JP-A-10-319358 is very different applicants', and there is no legally sound reason why one skilled in the art would attempt to use applicants' levels. Applicants' use of low levels for an undisclosed purpose and establishment of a new, effective, low concentration for a different utility, is *invention – not optimization*. Looking at it another way, it is not obvious to optimize an unknown.

It is also apparent that the prior art does not teach or suggest all the claim limitations. It does not teach applicants' concentrations, and it does not teach the effect attributed to the low concentration by applicants.

Significantly, there is no sufficient reason presented in the prior art to shift the burden of proof to applicants.

JP-A-10-319358 clearly teaches that the concentration of polyallylamine is at least 0.01 w/v% (at least 100 ppm), preferably at least 0.1 w/v% (at least 1,000 ppm), and is at most 10 w/v% (100,000 ppm), preferably at most 3 w/v% (30,000 ppm). In Examples 5 and 6 of the reference, polyallylamine is used, the concentrations of which are 1 w/v% (10,000 ppm) and 0.5 w/v% (5,000 ppm).

The Examiner has taken the view that the feature of concentration is merely determination of optimum concentration within the skill of the art in the absence of evidence to the contrary. However, it is apparent that at least the optimum concentration of polyallylamine taught by the reference is more than 1,000 ppm. The art suggests that for the only disclosed utility, higher concentrations within the effective range are better than lower concentrations. The cited references do not

provide any motivation for a person skilled in the art to use polyallylamine in the claimed concentration of 50 ppm or less.

Importantly, JP-A-10-319358 is directed to preserving the shape of contact lenses in the distribution process until patients purchase the lenses after the manufacturing. The reference use a solution which contains (I) polyallylamine and/or (II) a polymer such as a half amide of a maleic anhydride copolymer as a component for suppressing a change of the base curve of a contact lens at the time of the distribution. The references do not teach or suggest that the polyallylamine has an antibacterial activity.

The references do not provide any motivation or suggestion which leads a person skilled in the art to use polyallylamine at a lower level than the concentrations taught by the reference. It is not fair to assume that a person skilled in the art would have motivation to test for some undisclosed activity outside the disclosed range of operable concentrations.

A person skilled in the art will not find it obvious to optimize what is unknown.

### **C. Composition Claims 1-4 are Established by the Data as Unobvious**

Applicants' the data in the specification and declaration demonstrate the unexpected or unobvious nature of the claimed invention.

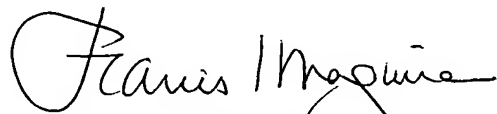
While applicants do not concede *prima facie* obviousness, the data is sufficient in nature and weight to establish unobviousness. The references do not teach or suggest that the polyallylamine has an antibacterial activity. Applicants note that the presence of a new utility for a novel composition, as done in this case, is wholly sufficient to overcome mere *prima facie* obviousness.

Even if one were to assume motivation to test for some activity outside the disclosed range of operable concentrations – which is not a fair assumption – for the sake of argument, it is not expected that a solution containing polyallylamine in a concentration of 0.3 to 50 ppm exhibits a high antibacterial activity. The data in

the specification and Declaration demonstrate that the claimed composition has a high antibacterial activity as compared with a conventionally used antibacterial agent "polyhexamethylene biguanide (PHMB)". The use of polyallylamine in a concentration of 0.3 to 50 ppm as an antibacterial agent is not optimization of the properties and amounts taught by the reference, since the claimed amount and the antibacterial activity are neither taught nor suggested by the reference.

Applicants have made a significant advance in the art and have described it in a manner that clearly distinguishes it patentably from the prior art. In addition, applicants have submitted evidence of unexpected results which is sufficient in nature and weight to overcome a rejection based on *prima facie* obviousness. Accordingly, reconsideration and withdrawal of the rejection and allowance of all pending claims are believed in order, and such actions are earnestly solicited.

Respectfully submitted,



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